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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,912	02/03/2006	Venkatram Prasad Shastri	RCHP-134US	4228
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RATNERPRESTIA			METZMAIER, DANIEL S	
P.O. BOX 980			ART UNIT	
VALLEY FORGE, PA 19482			PAPER NUMBER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/566,912

**Applicant(s)**

SHASTRI ET AL.

**Examiner**

Daniel S. Metzmaier

**Art Unit**

1796

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/3/06; 12/8/06; 1/29/07; 11/14/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-23 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/8/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-23 are pending.

#### ***Specification***

1. The abstract of the disclosure is objected to because the abstract should be in narrative form and generally limited to a single paragraph **on a separate sheet** within the range of 50 to 150 words. Correction is required. See MPEP § 608.01(b).

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for larger sized particles, does not reasonably provide enablement for the range having a lower limit of 0.001 nm, which is 0.01 angstroms. This is about 250 times smaller than nominal atomic radii and/or bond lengths. The claimed methods include polymers having MW of 30,000 or 70,000 (see page 5 of the instant specification), which would include at least hundreds of atoms and bonds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Tice et al, US 4,389,330. Tice et al (abstract ; column 2, lines 54 et seq ; column 3, lines 20 et seq ; examples ; and claims) disclose methods of microencapsulation employing an active ingredient and a wall material dissolved in a solvent system to form a solvent phase and dispersing said solvent phase into a continuous phase to form a microencapsulated material. Tice et al (column 4, lines 55 et seq) discloses the particles range from submicron levels, which by definition includes nanometer sized particles.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-9, 11-16 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tice et al, US 4,389,330 in view of Rickey et al, US 5,792,477. Tice et al (abstract ; column 2, lines 54 et seq ; column 3, lines 20 et seq ; examples ; and claims) disclose methods of microencapsulation employing an active ingredient and a wall material dissolved in a solvent system to form a solvent phase and dispersing said solvent phase into a continuous phase to form a microencapsulated material.

Tice et al (column 2, line 61) teaches suitable solvents include tetrahydrofuran, acetone and water. Tice et al (column 3, lines 20-33) teaches polymers including polylactides, polyglycolides, and copolymers thereof.

Tice et al differs from the claims in the exemplified use of a three solvent system polymer combinations and the characterization of the Drago polarities of said solvents.

Since Tice et al teaches the same solvents, albeit not necessarily together, as those instantly employed, the Drago polarities thereof would have been inherent.

Rickey et al (abstract; column 5, lines 29 et seq; column 6, lines 56 et seq) discloses the formation of microparticles employing methods similar to those of Tice et al and references Tice et al at column 2, lines 11 et seq of the Rickey et al specification.

Rickey et al (columns 6-7, lines 47-3) teaches the use of a co-solvent (e.g., benzyl alcohol) that is at least partially water-miscible and may further include ketones. Acetone is a ketone.

These references are combinable since Rickey et al references Tice et al as prior art. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ a cosolvent that is miscible with water as the third solvent in the process of Tice et al such as acetone.

Rickey et al (column 13, lines 60 et seq) teaches the use of a surfactant or a hydrophilic colloid to prevent the solvent microdroplets from agglomerating and to control the size of the solvent droplets and subsequent particles. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ a hydrophilic colloid other than polyvinyl alcohol in the process of Tice et al, such as polyacrylates or alginates.

#### ***Allowable Subject Matter***

9. Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: claim 10 would be allowable in independent form because the prior art does not teach or fairly suggest the claimed methods that are conducted without an emulsifying agent, a stabilizing agent and mechanical emulsification.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (571) 272-1089. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David W. Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Daniel S. Metzmaier/  
Primary Examiner, Art Unit 1796**

DSM